UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,365	01/18/2002	Mayumi Kotani	SAEGU92.001APC	7977

20995 7590 08/26/2003

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
JOYNES, ROBERT M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/26/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,365	KOTANI ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 7-23* is/are pending in the application.

4a) Of the above claim(s) *2-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 7-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicants' Preliminary Amendment and Information Disclosure Statement filed on January 18, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 7-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a composition and method for the prevention and/or treatment of type I allergies. **Claims 1 and 7-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of type I allergies ", does not reasonably provide enablement for "prevention of type I allergies". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.**

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, and the working examples. All the factors

have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention: All rejected claims are drawn to the method of treating or preventing type I allergies in a subject with the administration of the instant composition. The nature of the invention is extremely complex in that it encompasses anticipating the location of the allergy, how different allergies will react to the allergy inhibition, how different allergies will be effected, how skin allergies will be treated in the same manner as bronchial allergies and subsequently administering instant composition such that the subject treated will not have adverse side effects or no effects at all.

Breadth of Claims: The complex nature of the claims is greatly exacerbated by the breadth of the claims. The claim encompasses prevention of multiple complex allergies in which all type I allergies are prevented since the disease may be caused and treated by other means. This may or may not be addressed by the administration of the composition.

State of the Art: The state of the art does not recognize the administration of astragalin to prevent type I allergies. The state of the art recognizes the treatment of the symptoms of these allergies but not the cure of the allergies.

Guidance of the Specification: The guidance given by the specification on how to anticipate type I allergies and their location to prevent the allergies is absent.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to completely envisioning/anticipating type I allergies and preventing type I allergies in a human subject with the administration of the instant

composition makes practicing the claimed invention unpredictable in terms of the prevention of the disease.

The Amount of Experimentation Necessary: In order to practice claimed invention, one of ordinary skill in the art would have to first to anticipate type I allergies, their location, the effective dosage, duration of treatment, etc. to determine whether or not the instant composition prevents the allergies. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art, one of ordinary skill in the art would have to either envision a modification of the variable factors or envision an entirely new combination of the factors, and test the invention again. If unsuccessful again, the whole process would have to be repeated until invention was shown to be successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention.

For these reasons the claim is rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 7-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over H. Fukumoto et al., Anti-anaphylactic Effects of the Principal Compounds from the White Petals of Impatiens balsamina L., Phytotherapy Research, Vol. 10, 1996, pp.202-206 in combination with Sawruk (US 5478579).

Fukumoto teaches kaempferol-3-glucoside is known as an anti-anaphylactic agent (See entire document). Further, the compounds taken from white petals of Impatiens balsamina L. inhibit IgE-mediated anaphylaxis (See Introduction). The compounds extracted were used to treat allergic reactions on skin (See entire document). Fukumoto does not expressly teach pharmaceutical compositions for the compounds extracted.

Sawruk teaches flavonol aglycone glycosides in pharmaceutical formulations (Col. 2, lines 1-17). One such compound is astragalin (Col. 2, lines 53-62). The dosage for the compounds is 50-250 mg/daily dose but will vary depending on age weight, health and sex of the patient and can be administered 2 to 3 times a day (Col. 4, lines 1-14). The compounds can be formulated in various pharmaceutical compositions with conventional pharmaceutical excipients (Col. 4, lines 15-43). Sawruk does not expressly teach the same exact concentration ranges of the astragalin but does teach a range that overlaps and/or encompasses the ranges recited in the instant claims. It is the position of the Examiner that the prior art teaches oral compositions and no criticality is seen in the composition being a food product.

With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a pharmaceutical formulation comprising astragalin that can be used to treat allergies, specifically skin allergies.

One of ordinary skill in the art would have been motivated to do this to deliver the active compound in a manner that will best achieve the result of alleviating the allergic reactions.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
August 25, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600